

REMARKS

Claims 90-107 are pending in the present application. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. Applicants have limited the pending claims to method claims solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), 65 Fed. Reg. 54603 (September 8, 2000) without prejudice or disclaimer to the canceled subject matter. Applicants maintain the right to re-prosecute the canceled subject matter in a later filed divisional application. Non-elected subject matter has also been removed from the scope of the claims. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Rejections Under 35 U.S.C. § 102(b)

The Official Action states that the "rejection of claims 3-8, 11, 14-25 under 35 USC 102(b)...in the previous office action is maintained for amended claims 4, 7, 21-24 for reasons of record". However, only canceled compound claims 1 and 2 were rejected under 35 U.S.C. § 102(b) in the previous office action; none of claims 3-8, 11, and 14-25 were rejected under 35 U.S.C. § 102(b). Accordingly, applicants respectfully point out to the

Examiner that none of the presently pending method claims 90-107 stand rejected under 35 U.S.C. § 102(b).

2. Rejection of Claims 4, 7, and 21-24 under 35 U.S.C. § 103(a)

The Official Action states that the rejection of claims 4, 7, and 21-24 under 35 U.S.C. § 103(a) as being obvious over CA 89:215152 (Busson et al.) has been maintained. In particular, the Examiner now finds claims 4, 7, and 21-24 to be obvious over Busson et al. in view of WO 92/21313 (the '313 publication), Patani et al., and BIOSIS 05620415. Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the U.S. Patent and Trademark Office must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Notwithstanding the lack of motivation to modify or the lack of a reasonable expectation of success of such modification, the references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. Regarding presently pending claims 90-107, applicants have already pointed out to the Examiner that the claims are directed to methods of treating neurological disorders in an animal. The cited reference does not in any way teach or suggest treating neurological disorders. The '313 publication, Patani et al., and BIOSIS 05620415 do not remedy this deficiency.

None of the '313 publication, Patani et al., and BIOSIS 05620415 disclose the ability of any of the embodied compounds to treat a neurological disorder in an animal. The Examiner's statement that "the esters which is known in the art to have the same utility as the claims (WO 92/21313)" is incorrect. The '313 publication is directed to esters having immunosuppressive abilities. Nowhere does the '313 publication state that the disclosed compounds have any neurotrophic abilities whatsoever. Accordingly, the disclosures of Busson et al., the '313 publication, Patani et al., and BIOSIS 05620415, even when taken together, do not teach every limitation of the presently claimed invention as required by *In re Wilson*.

Accordingly, applicants respectfully request the Examiner to

reconsider and withdraw the final rejection of remaining claims 90-107.

**3. Rejection of Claims 5, 8, and 11 under
35 U.S.C. § 112, 2d paragraph**

The Official Action states that claims 5, 8, and 11 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The claims 5, 8, and 11 have been amended to remove the references to the specification by compound number and to incorporate the structure for each particularly claimed species.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the final rejection of remaining claims 90-107.

**4. Rejection of Claims 3-8, 11, 14-25, and 72-89 under
35 U.S.C. § 102(g), 102(e), or 103(a)**

The Official Action states that claims 3-8, 11, 14-25, and 72-89 are rejected under 35 U.S.C. § 102(g), 102(e), or 103(a) as being unpatentable over Bull et al. WO 99/45006. Applicants respectfully traverse this rejection. Applicants respectfully submit to the Examiner that the claims are novel and unobvious over the cited reference.

With respect to the rejection under 35 U.S.C. § 102(g), the

statute states that:

"A person shall be entitled to a patent unless before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other." (Emphasis added)

Accordingly, Bull et al. is available as a reference under 35 U.S.C. § 102(g) only as of its date of filing in the United States. See Also *In re Hilmer II*, 165 USPQ 255, 258 (C.C.P.A. 1970).

Bull et al. is a PCT publication claiming priority to an application filed in Great Britain. All of the named inventors in the cited reference are citizens of Great Britain. There is no evidence that a corresponding application has been filed in this country. Accordingly, Bull et al. is an improper reference under 35 U.S.C. § 102(g). Even if a corresponding U.S. application has been or is to be filed, it would bear a U.S. filing date equal to that of the international filing date, i.e. February 15, 1999. This date falls after applicants priority date of June 3, 1998 and filing date of December 3, 1998.

"Section 119 must be interpreted as giving only a positive right or benefit to an applicant who has first filed abroad to *protect him* against possible intervening patent-defeating events

in obtaining a patent." *In re Hilmer I*, 149 USPQ 480, 496 (C.C.P.A. 1966). Accordingly, even though a potential U.S. patent application corresponding to Bull et al. would be entitled to the benefit of the British filing date, this application would not acquire "that same date under § 102(g) as patent-defeating prior art, in direct contravention of the 'in this country' limitation of the section." *In re Hilmer II*, 165 USPQ 255, 258 (C.C.P.A. 1970).

Accordingly, Bull et al. is an invalid 102(g) reference against the present application.

With respect to the rejection under 35 U.S.C. § 102(e), the statute states that:

"A person shall be entitled to a patent unless the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent." (Emphasis added)

In the present rejection, Bull et al. is a PCT publication rather than a U.S. patent as required by statute. Accordingly, Bull et al. is an invalid piece of prior art against the present invention under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a).

Additionally, under MPEP § 2136.03, a reference's foreign priority date under 35 U.S.C. § 119(a)-(d) cannot be used as the

35 U.S.C. § 102(e) reference date. Only the reference's international filing date can be used as the 35 U.S.C. § 102(e) reference date. The Bull reference bears an international filing date of February 15, 1999, after applicants priority date of June 3, 1998 and filing date of December 3, 1998. Accordingly, Bull et al. is an invalid 102(e)/103(a) reference against the present application.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the final rejection of remaining claims 90-107.

**5. Rejection of Claims 3-8, 11, 14-25, and 72-89 under
35 U.S.C. § 102(g), 102(e), or 103(a)**

The Official Action states that claims 3-8, 11, 14-25, and 72-89 are rejected under 35 U.S.C. § 102(g), 102(e), or 103(a) as being unpatentable over WO 99/14998 ('998 publication).

Applicants respectfully traverse this rejection. Applicants respectfully submit to the Examiner that the claims are novel and unobvious over the cited reference.

Regarding the rejection under 35 U.S.C. § 102(g), the statute reads as stated above in Section 4, the arguments of which are hereby incorporated by reference in their entirety. Accordingly, applicants respectfully point out to the Examiner that the '998 publication is directed solely to methods for preventing or treating sensorineural hearing loss. In this regard, the

Examiner's attention is directed to claim 1, which reads "A method for the prevention or treatment of sensorineural hearing loss..." In contrast, all of presently pending claims 90-107 are directed to methods of treating a neurological disorder. Accordingly, applicants presently claimed invention can not be found in the '998 publication and the presently claimed invention is novel under 35 U.S.C. § 102(g).

The '998 publication is a PCT publication rather than a U.S. patent as required by statute. Accordingly, the '998 publication is an invalid piece of prior art against the present invention under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a).

Regarding the U.S. application corresponding to the '998 publication, under MPEP § 706.02(k), "where two applications of different inventive entities are copending and the filing dates differ, a provisional rejection under 35 U.S.C. 102(e)/103 should be made in the later filed application if the applications have a common assignee or a common inventor. Otherwise the confidential status of applications under 35 U.S.C. 122 must be maintained." The cited reference has neither a common assignee nor a common inventor with the present application. Furthermore, the Examiner cannot provide a copy of the currently pending application so that applicants can review the relevance of the reference without violating the confidential status of applications under 35 U.S.C.

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Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the final rejection of remaining claims 90-107.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the final rejections of the remaining claims and allow all pending claims 90-107 presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,
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